

Paradigm™

VPS Impression Materials

ENGLISH

Product Description

Paradigm™ VPS Impression Materials are composed of hydrophilic vinyl polysiloxane impression materials, designed for making precise crown and bridge, inlay, onlay, veneer preparations, removable denture and partial denture impressions. The Paradigm™ Heavy Body Impression Material is formulated for use with the Paradigm™ Light Body Impression Material and Paradigm™ Regular Body Impression Material, to meet the demands of the two viscosity technique. The Paradigm™ Monophase Material is formulated to meet the demands of the Monophase Impression technique, in a custom full arch, quadrant and double arch tray. The one minute oral working time allows the dentist to syringe one to four units. It may be used in cases where there are more than four adjacent preparations, provided the tray is seated within 1 minute from the start of oral syringing. Paradigm monophase impression material can be used as a tray material with the Paradigm light body impression material, as the syringeable material.

Paradigm™ VPS Fast Set Heavy Body / Light Body Impression Material is a fast, rigid setting hydrophilic dental impression material designed for making a precise impression of an inlay, onlay, veneer, or crown. Paradigm fast set heavy body and light body impression materials are formulated for use in a one-step/two viscosity impression technique. Paradigm heavy body can be used in combination with Paradigm fast set regular body or light body impression material. The Paradigm fast set heavy body impression material has 1:15 minutes of room temperature working time with an oral setting time of 2:30 minutes. The Paradigm fast set regular and light body impression materials have 40 seconds of oral working time and an oral setting time of 2:30 minutes.

IMPORTANT, PLEASE NOTE:

Paradigm VPS Fast Set impression material has 40 seconds of oral syringing time, and it is designed for use in fast procedures where the impression tray can be seated within 40 seconds from the start of oral syringing. This material is designed for a single unit, but can be used in some cases for up to three adjacent units. **Do not syringe more than three adjacent units.** To avoid incomplete or inaccurate impressions, be careful not to exceed the 40 seconds of oral working time.

Due to the rigidity and short working time of the impression materials, the following trays are recommended.

Dual Arch – Metal and Disposable trays

- Anterior
- Quadrant
- Posterior with sides

As with any rigid-setting impression material, it may be necessary to block-out undercuts or areas where gingival recession exists to prevent the material from “locking” on to tooth structure. Failure to block-out may make tray removal difficult or cause extraction of natural teeth or prosthesis.

Areas of Application

Precise crown and bridge, inlays, onlay, veneer preparations, removable denture and partial denture impressions.

Preparation

Impression trays:

1. Particularly suitable are rigid trays or custom plastic trays. Blocking of the distal edge of the tray with a silicone or thermoplastic material provides for controlled flow properties affording beneficial effects especially for the distal molar area.
2. The use of a VPS tray adhesive for sufficient adhesion is recommended. Apply a thin layer of adhesive to the tray and allow to dry a minimum of 5 minutes.

Note: The use of mix tips manufactured by SULZER MIXPAC® is required to ensure proper performance of the material.

Dispenser/cartridge:

1. Place the Paradigm heavy body, light body or regular body impression material into the hand-dispenser.
2. Dispense/bleed a small amount of impression material until both the base and catalyst emerge uniformly, then attach a green mix tip for the Paradigm heavy body impression material, and a yellow mix tip for the Paradigm light body and regular body impression materials.
3. For intraoral use of Paradigm light body, or Paradigm regular body, attach a yellow intraoral tip to the yellow mix tip. (**Note:** Use moderate pressure and push the blunt end of the intraoral tip into the mix tip. A click will be heard when the intraoral tip is locked into position). Alternatively, dispense the Paradigm light body or regular body material into an intraoral syringe.

Retraction

Areas from which impressions are to be taken should be kept dry but not desiccated. In subgingival preparations, hemostatic threads or rings may be used. Prior to taking the impression, completely remove any residue of the retraction agent by rinsing and drying.

Dosing and Mixing

Dosing and mixing are performed automatically with the hand-dispenser for the Paradigm heavy body, Paradigm light body, or Paradigm regular body impression materials. The mixing ratio is 1 volume base paste to 1 volume catalyst for the cartridge system.

Times in Minutes:	Room Temperature Working Time	Intraoral Setting Time
Paradigm™ Heavy Body Material	2:00	4:00
Paradigm™ Fast Set Heavy Body Material	1:15	2:30
Paradigm™ Light or Regular body material	1:00	4:00
Paradigm™ Fast Set Light or Regular Body Material	0:40	2:30
Paradigm™ Monophase Material	2:00	4:00

Note: Once the tray is seated in the mouth, it is not necessary to add any unused work time to the 4 minute (2:30 minutes for fast set) oral set time.

Impression Taking

One-Step/Two Viscosity Impression Technique:

Recommended Materials: Paradigm fast set heavy body impression material in combination with Paradigm fast set regular body or light body impression materials.

Bleed both materials before each use. This action will reduce the occurrence of plugging.

1. Place Paradigm heavy body impression material into the hand-dispenser.
2. While the assistant loads the tray, the dentist may begin to syringe light body or regular body impression material around the preparation. Depending on the number of teeth, initiate application such that tray loading and application of the wash material around the preparations are completed at the same time. During application, the mix tip should be immersed in the material at all times to avoid trapping air bubbles. **The maximum tray filling time is 1:15 minutes for Paradigm Fast Set heavy body impression material. The tray must be seated within 40 seconds from the start of syringing the Fast Set light body impression material.**
3. Slowly place the loaded tray in the mouth parallel to the vertical axes of the prepared teeth. Once the tray is seated, hold in place without applying pressure for 4 minutes. Avoid contact of the teeth with the tray.
4. After 4 minutes (2:30 minutes for fast set), apply pressure along the periphery of the impression tray to break the seal of the impression. The impression can then be removed from the mouth.
5. Thoroughly examine and explore the margins of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

Two-Step/Two Viscosity Technique:

Recommended Materials: Paradigm heavy body impression material in combination with Paradigm light or regular body impression materials. **Bleed both materials before each use. This action will reduce the occurrence of plugging.**

1. Fill the impression tray with Paradigm heavy body impression material.
2. Place a plastic spacer over the mixed heavy body material and seat the tray in the mouth. Maneuver the tray in the mouth to create a 2-3 mm space between the teeth and impression material.
3. Remove the tray after 4 minutes and discard the spacer.
4. Trim out any undercuts and interdental appendages for a distortion free seating.
5. Syringe the Paradigm light body or regular body material into the spaces of the preliminary impression and around the prepared teeth.
6. Re-seat the tray, being careful to avoid contact of the teeth with the pre-set heavy body impression material. **Note:** The tray must be seated within one minute from the start of oral syringing.
7. Once the tray is seated, hold in place without applying pressure for 4 minutes (2:30 minutes for fast set).
8. After 4 minutes (2:30 minutes for fast set), apply pressure along the periphery of the impression tray to break the seal of the impression.
9. Thoroughly examine and explore the margins of the prepared teeth and surrounding dentition. Remove any residual cured impression material from the mouth.

Monophase Technique:

Recommended Materials: Paradigm Monophase material in combination with Paradigm Monophase impression material. **Bleed both materials before each use. This action will reduce the occurrence of plugging.**

1. Select or prepare a rigid tray of sufficient size and wall height to accommodate 2-3 mm thickness of impression material surrounding the teeth.
2. Brush a thin coat of VPS adhesive on to the tray and allow to air dry a minimum of five minutes.
3. Prepare the teeth, isolate and place retraction cord(s).
4. Attach a green tip; using full firm strokes of the dispenser, fill the entire adhesive-coated tray with Paradigm monophase impression material; fill the tray with Paradigm monophase material, while keeping the tip immersed in the dispensed material to avoid trapping air.
5. For syringing around prepared teeth, dispense Paradigm monophase impression material into an intraoral syringe. Alternatively, syringing may be accomplished directly from the cartridge by attaching an intraoral tip to the mix tip.
6. Remove retraction cord(s) and inject the Paradigm monophase impression material around the clean, dry tooth preparation(s). Syringe with a stirring motion, keeping the tip immersed to avoid entrapping air and to ensure complete coverage of the prepared surfaces.
7. Seat the tray, being careful to avoid contact of the teeth with the tray. **Note: The tray must be seated within 1 minute of the start of oral syringing and within 2 minutes of the start of tray filling.**
8. Immobilize the tray in the mouth using passive pressure. **Oral Setting time is a minimum 4:00 minutes.**
9. Apply downward pressure along the periphery of the tray to break the seal of the impression and remove the impression from the mouth.
10. Visually inspect the impression for completeness and ensure there are no remnants remaining in the mouth.
11. Rinse the impression completely of oral fluids, and place into liquid disinfectant for the time prescribed by the manufacturer and or Centers for Disease Control and Prevention's, Guidelines for Infection Control in Dental Health-Care settings – 2003 (Vol. 52; No RR-17).
12. After removal from the disinfectant, rinse to remove disinfectant residue. The stone model may be poured 30 minutes after the completed disinfection process. The Paradigm impression materials are very stable and may be left to pour up to two weeks after setting is complete.
13. Impression should be shipped in designed packaging to prevent distortion and contamination.

Cautions:

1. Check cartridge portals for plugging before attaching the mix tip. At the onset of mixing, closely monitor the entry of paste into the mixing tip and ensure that both base paste and catalyst paste flow into the mixing tip.
2. Avoid surface contact or contamination with chemicals known to inhibit the set (e.g. acrylic and methacrylate residues, sulfur compounds from latex rubber gloves). If acrylic and methacrylate resin residues are present, clean the affected tooth surface with isopropyl alcohol before making the impression. To avoid inhibition caused by custom temporary materials, the final impression should be made before fabricating the provisional restoration. If contamination from latex rubber or sulfur is suspected, rinse the area with an aqueous solution of hydrogen peroxide before making the impression.
3. The oxygen inhibition layer of composite materials, e.g. in fillings or core buildups, may impair the setting of silicone materials, and should therefore be removed completely.
4. Premature exposure of the syringe material to the higher temperature of the mouth causes this material to set more rapidly than the tray material. This may distort the impression.
5. Load the impression tray, and then insert into the mouth proceeding slowly and along the vertical axes.
6. As with any rigid setting impression material, if undercuts or gingival recession are noted, blocking out may be required to prevent the material from "locking" onto tooth structure. Failure to do so may make tray removal difficult, or cause extraction of natural teeth or prosthesis.
7. Paradigm heavy body material is not recommended for use as a syringeable wash material.

Hygiene

Disinfect the product using an intermediate level disinfection process (liquid contact) as recommended by the CDC and endorsed by the ADA, Guidelines for Infection Control in Dental Health-Care Settings – 2003 (Vol. 52; No. RR – 17), Centers for Disease Control and Prevention. After disinfecting, immediately rinse the impression in water and blow dry.

Model Preparation

When using Paradigm heavy body impression material, the stone model may be poured immediately after disinfection. The impressions can be silver or copper-plated.

Impressions made using Paradigm VPS impression materials are very stable and may be poured up to two weeks post polymerization.

Cleaning

1. Disassemble the hand-dispenser, and sterilize the dispenser handle and plunger separately at up to 135°C/275°F or with commercial cleaning agents containing no strong organic solvents, such as alcohols. **Do not use disinfectants.**
2. Pastes that have not set may be removed with ethanol. The adhesive can be removed from metal trays with acetone.

NOTE: CAREFULLY READ AND FOLLOW THE CLEANING SOLVENT MANUFACTURER'S PRECAUTIONS AND DIRECTIONS FOR USE.

Notes

1. The oxygen inhibition layer of composite materials, e.g. in fillings or core buildups, may impair the setting of silicone materials, and should therefore be removed completely.
2. Keep the filled mixing tip on the cartridge to serve as a closure until the next use. Storage with a new mixing tip may lead to carry-over of paste and or air may cause a plug to form in the cartridge.
3. Some disposable latex gloves may impair the setting of impression materials. Hence, vinyl or nitrile gloves are more suitable.

Technical Data

The impression materials comply with ISO 4823.

Paradigm™ Impression Material	Heavy Body & FS	Regular Body & FS	Light Body & FS	Monophase
Strain in compression (%):	2.5	2.7	3.0	2.3
Recovery from deformation (%):	> 99.0	> 99.0	>99.0	>99.0
Linear dimensional change (after 24 h) (%):	0.3	0.20	0.20	<0.2

Storage and Stability

This product is designed to be stored and used at room temperature. Shelf life at room temperature is 24 months. Ambient temperatures routinely higher than 80°F/27°C or lower than 35°F/2°C, may reduce shelf life. See outer package for expiration date.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Caution: U.S. Federal Law restricts this device to sale or use on the order of a dental professional.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

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44-0007-4964-6-A

